11.17

| N THE UNITED STATES PATENT AND TRADEMARK OFFICE

In PANE Application of:

Atty. Docket No.:

161765.00004

(00898/1/US)

RUDOLPH et al.

Serial No.:

10/645.564

Group Art Unit:

TBA

Filed:

August 22, 2003

Examiner:

TBA

For:

Modulation of Matrix Metalloproteinase (MMP) Activity With Aldosterone

Blocker(s)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to their duty of good faith and candor as set forth in 37 C.F.R. §§ 1.56(a), 1.97 and 1.98 et seq., Applicants submit herewith the attached Form PTO/SB/08A. Applicants have submitted each of the references cited on the attached Form PTO/SB/08A with this paper. Applicants respectfully request that the Examiner consider and enter all the documents cited on the enclosed Form PTO/SB/08A into the file of the above-identified application. Applicants also request an indication of the same by return of the Form PTO/SB/08A being initialed and dated by the Examiner.

No fees are believed due to ensure consideration of the attached documents by the Examiner. However, if any fees are required or an overpayment of fees made, the Commissioner is hereby authorized to debit or credit our Deposit Account No. 19-0733, as necessary.

Respectfully submitted,

Date: January 21, 2004

By:

Ajay Pathak

Registration No. 38,266

BANNER & WITCOFF, LTD. 1001 G Street, N.W., 11th Floor Washington, D.C. 20001 (202) 824-3000 (202) 824-3001 (fax)

Attachments:

Form PTO/SB/08A
References Cited on Form PTO/SB/08A

547941 1.DOC

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449A/PTO C mplete if Known **Application Number** 10/645,564 **物尼ORMATION DISCLOSURE**

STATEMENT BY APPLICANT 1 2004

of

Filing Date August 22, 2003 RUDOLPH et al. First Named Inventor Group Art Unit **TBA Examiner Name TBA**

(use finany sheets as necessary) Sheet

161765.00004 (00898/1/US) Attorney Docket Number

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No.1	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
			MM-DD-YYYY			
	_	US-				
		US-				
		US-				
		US-				
		US-				
		US-				

Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)				
	1.	WO 01/05389 A2	01/25/01			
	2.	WO 01/05756 A1	01/25/01			
	3.	WO 01/12611 A1	02/22/02			
	4.	WO 01/38301 A1	05/31/01			
	5.	WO 01/85680 A2	11/15/01			
						

OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	6.	Sabbah, H.N., Shimoyama, H., Kono, T., Gupta, R.C., Sharov, V.G., Scicli, et al. Effects of long-term monotherapy with enalapril, metropolol, and digoxin on the progression of left ventricular dysfunction and dilation in dogs with reduced ejection fraction. Circulation 89 (1994):2852-2859		
	7.	Sabbah, H.N., Stanley, W.C., Sharov, V.G., Mishima, T., Tamimura, M., Benedict, et al. Effects of dopamine β-hydroxylase inhibition with nepicastat on the progression of left ventricular dysfunction and remodeling in dogs with chronic heart failure. Circulation 102 (2000): 1990-1995		
	8.	Chadwick, V., Thomas, B.S., Mytsi, L., Coker, B.A., Zellner, J.L, Handy, J.R., et al. Increased Matrix Metalloproteinase Activity and Selective Upregulation in LV Myocardium From Patients with End-Stage Dilated Cardiomyopathy. Circulation 1998: 97: 1708-1715		

Examiner Signature	Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1460, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1450.

Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

10/645,564

aperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Substitute for form 1449A/PTO Complete if Known

Application Number

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

August 22, 2003 First Named Inventor RUDOLPH et al. **Group Art Unit TBA** (use as many sheets as necessary) **TBA Examiner Name**

Filing Date

Sheet 2 161765.00004 (00898/1/US) of Attorney Docket Number

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	9.	Lijnen, H.R.: Plasmin and matrix metalloproteinases in vascular remodeling, <i>Thromb. Haemost.</i> 86:324-333 (2001)	
	10.	Shah, P.K., Galis, Z.S.: Matrix metalloproteinase hypothesis of plaque rupture: players keep piling up but questions remain, Circulation 104:1878-1880 (2001)	
	11.	George, S.J.: Therapeutic potential of matrix metalloproteinase inhibitors in atherosclerosis, Expert Opin. Investig. Drugs, 9(5):993-1007 (2000)	
	12.	Creemers, E.E., Cleutjens, J.P., Smits, J.F., Daemen, M.J.: Matrix metalloproteinase inhibition after myocardial infarction: a new approach to prevent heart failure? Circ. Res. 89:201-210 (2001)	
	13.	Terrence M. Doherty, et al., Therapeutic Developments in Matrix Metalloproteinase Inhibition, review article, Expert Opin. Cir. Patents, 12(5) pp. 665-707, Ashley Publications (2002)	
	14.	Li, Y.Y., Feng, Y., McTiernan C.F., et al., Downregulation of matrix metalloproteinase and reduction in collagen damage in the failing human heart after support with left-ventricular assist devices, Circulation, 104:1147-1152 (2001)	
	15.	Mann D.L., Taegtmeyer H., Dynamic regulation of the extracellular matrix after mechanical unloading of the failing human heart: recovering the missing link in left ventricular remodeling, Circulation, 104:1089-1091 (2001)	
	16.	Lee, R.T., Matrix metalloproteinase inhibition and the prevention of heart failure, <i>Trends Cardiovasc. Med.</i> , 11:202-205 (2001)	
	17.	Kim, H.E., Dalal, S.S., Young, E., Legato, M., Weisfeldt, M.L., D'Armento J., Disruption of the myocardial extracellular matrix leads to cardiac dysfunction, J. Clin. Invest., 108:857-866 (2000)	
	18.	Spinale, F.G., Coker, M.L., Bond, B.R., Zellner, J.L., Myocardial matrix degradation and metalloproteinase activation in the failing heart: a potential therapeutic target, Cardiovasc. Res., 46:225-238 (2000)	
	19.	Etoh, T., Joffs, C., Deschamps, A.M. et al., Myocardial and interstitial matrix metalloproteinase activity after acute myocardial infarction in pigs, Am J. Physiol. Heart Circ. Physiol. 281:H987-H994 (2001)	
	20.	Stary, H.C., The sequence of cell and matrix changes in atherosclerotic lesion of coronary arteries in the first forty years of life, Eur. Heart J. 11(Suppl. E) 3:19 (1990)	
	21.	Ducharme, A., Frantz, S., Aikawa, M., et al., Targeted deletion of matrix metalloproteinase-9 attenuates left ventricular enlargement and collagen accumulation after experimental myocardial infarction, J. Clin Invest. 106:55-62 (2000)	

Examiner	Date	
Signature	Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1460, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1450.

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.